

OCT - 9 1996

Heelbo, Inc.
Great Hands Mitts

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter

Heelbo, Inc.
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Contact Person

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Date Summary Prepared - July 15, 1996

2. Name of Device:

Great Hands Mitts

3. Name of Predicate Device(s)

Great Hands Mitts

4. Description of Device

Great Hands Mitts are hand restraints that are worn like gloves. The cotton covered mitt is filled with polyester and is covered with a mesh material on one side. The glove-like finger lanes are sewn into the mesh material and a Velcro wrist strap with a D-Ring loop fastener helps secure the glove in place.

The mitts are intended to prevent patients from grasping or pulling out catheters, I.V. tubes and other vital lines. The mitts also prevent patients from scratching themselves or inflicting other injuries to themselves or others.

The Great Hands Mitts are available in one size, and three colors to accommodate adult hands and three sizes, three colors to accommodate infants, toddlers and youths. Below is the listing of stock numbers and availability.

Stock Number	Description	Color
1000, 1000HP, 1000N	adult	white, hot pink, navy
1110, 1110HP, 1110N	infant	white, hot pink, navy
1120, 1120HP, 1120N	toddler	white, hot pink, navy
1130, 1130HP, 1130N	youth	white, hot pink, navy

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5. Statement of Intended Use

Great Hands Mitts hand restraints are worn like gloves. The mitts are intended to prevent patients from grasping or pulling out catheters, I.V. tubes and other vital lines. The mitts also prevent patients from scratching themselves or inflicting other injuries to themselves or others.

6. Statement of Technological Characteristics of the Device

Great Hands Mitts are hand restraints that are worn like gloves. The cotton covered mitt is filled with polyester and is covered with a mesh material on one side. The glove-like finger lanes are sewn into the mesh material and a Velcro wrist strap with a D-Ring loop fastener secures the glove in place.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft "Guidance on the Content of Premarket Notification [501(k)] Submissions for Protective Restraints" dated December 1995.

7. Biocompatibility Assessment

The subject devices are identical in component materials to the predicate devices. The suppliers of the materials use in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

9. Conclusion

Based upon the information presented above it is concluded that the Heelbo Great Hands Mitts are safe and effective for their intended use and are substantially equivalent to the predicate device.